GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5637
ANSWERED ON:07.04.2017
Regulations of Diagnostic Laboratories
Boianapalli Shri Vinod Kumar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the diagnostic laboratories industry in India is unregulated and most of the States have not adopted/implemented Clinical Establishments Act, 2010 and if so, the details thereof;

(b) whether as per the NABL website, less than 1 per cent of the total laboratories are accredited; and

(c) if so, the details thereof and the reasons therefor?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a): Health is a State subject and regulation of diagnostic laboratories falls within the remit of State Governments. The Government of India has, however, enacted the Clinical Establishments (Registration and Regulation) Act, 2010 (CEA) and notified Clinical Establishments (Central Government) Rules, 2012 for registration and regulation of Clinical Establishments, including Diagnostic Laboratories. The Act is currently applicable in ten(10) States namely, Arunachal Pradesh, Mizoram, Himachal Pradesh, Sikkim, Jharkhand, Bihar, Rajasthan, Uttarakhand, Uttar Pradesh and Assam and all Union Territories except Delhi. Other States and Union territory of Delhi have not adopted the Act as yet. Implementation of this Act is also within the purview of the States/Union Territories.

(b) & (c): Accreditation is a voluntary process and cannot be a basis for regulation. As per the information made available by the Quality Council of India, 816 Medical Testing Laboratories have been accredited by NABL.